

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 14-2220

DAVID S. ZINK, MICHAEL WORTHINGTON, LEON TAYLOR, WALTER T. STOREY, EARL RINGO, RODERICK NUNLEY, PAUL T. GOODWIN, ANDRE COLE, REGINALD CLEMONS, CECIL CLAYTON, MARK A. CHRISTESON, RUSSELL EARL BUCKLEW, DAVID M. BARNETT, RICHARD STRONG, MARCELLUS WILLIAMS,

Appellants,

v.

GEORGE A. LOMBARDI, Director, Missouri Department of Corrections, DAVID DORMIRE, Director, Division Adult Institutions, Missouri Department of Corrections, MATTHEW BRIESACHER, Counsel, Missouri Department of Corrections, TERRY RUSSELL, Warden, Eastern Regional Diagnostic & Correctional Center, JOHN DOES 2-40

Appellees.

Appeal from the United States District Court
for the Western District of Missouri, Central Division,
The Honorable Beth Phillips, District Judge

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SUMMARY AND REQUEST FOR ORAL ARGUMENT

Appellants are Missouri death-sentenced prisoners who bring constitutional and other claims against the state's method of lethal injection. In two separate orders, the United States District Court for the Western District of Missouri dismissed all claims in the prisoners' second amended complaint, for failure to state a claim on which relief can be granted. Add. 1-26. Because of the numerous claims involved, as well as their factual complexity, appellants respectfully request oral argument of thirty minutes per side.

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JURISDICTIONAL STATEMENT

Appellants sought declaratory and injunctive relief on claims that Missouri's method of lethal injection is unconstitutional in numerous respects and that it violates federal drug statutes and regulations as made cognizable under the Missouri Administrative Procedure Act. In two orders, the district court granted the defendants' motion to dismiss the second amended complaint. Add. 1-26. The district court entered its final order and judgment on May 16, 2014, and the plaintiffs filed their notice of appeal six days later. App. 53-54. The district court's final order denied, as moot, the motions to intervene filed by death-sentenced prisoners Marcellus Williams and Richard Strong. Add. 26. Messrs. Williams and Strong filed a separate notice of appeal on June 3, 2014, App. 54, and the Court granted their separate motions to intervene as appellants in this case on June 23, 2014. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

I.

Whether the district court erred by dismissing the prisoners' Eighth Amendment claim solely for the lack of a "reasonably available" and pain-reducing alternative method of execution within the complaint itself, and following the prisoners' inability to obtain any discovery concerning what methods or drugs are "reasonably available" to the Missouri Department of Corrections

Bucklew v. Lombardi, 134 S. Ct. 2333 (2014)

Hill v. McDonough, 547 U.S. 573, 582 (2006)

Jones v. Bock, 549 U.S. 199, 213 (2007)

Baze v. Rees, 553 U.S. 35, 51-52 (2008)

In re Lombardi, 741 F.3d 903, 905 (8th Cir. 2014)

II.

Whether the district court wrongly dismissed the prisoners' First Amendment claim arising from the defendants' concealment of the source and provenance of the drugs to be used to kill them, when the information sought relates to historically open procedures and its suppression interferes with the prisoners' First Amendment rights

Sorrell v. IMS Health Inc., 131 S.Ct. 2653 (2011)

Globe Newspaper Co. v. Superior Court, 457 U.S. 596, 604 (1982)

Press-Enterprise Co. v. Superior Court, 478 U.S. 1, 8-14 (1986)

California First Amendment Coalition v. Woodford, 299 F.3d 868, 877 (9th Cir. 2002)

III.

Whether the district court erroneously dismissed the prisoners' claims that the defendants' protocol violates federal drug laws that do not provide a private right of action, despite an aggrieved party's ability to sue a Missouri agency under the state Administrative Procedure Act when the agency's action is "unlawful"

Mo. Rev. Stat. § 536.150.1

Strong v. American Cyanamid Co., 261 S.W.3d 493, 516-17 (Mo. Ct. App. 2007)

IV.

Whether, in light of the risks from compounded drugs that are documented by the prisoners' experts, the prisoners bring a viable *ex post facto* claim based on the state's change from FDA-regulated execution drugs to an unregulated compounded drug in violation of federal law

Garner v. Jones, 529 U.S. 244, 253-55 (2000)

In re Lombardi, 741 F.3d 888, 896-97 (8th Cir. 2014) (en banc)

V.

Whether due process entitles the prisoners to timely information about the drug that will be used to execute them, as well as information concerning any "reasonably available" alternatives that the district court required them to plead

Fuentes v. Shevin, 407 U.S. 67, 80 (1972)

Mathews v. Eldridge, 424 U.S. 319, 335 (1976)

VI.

Whether the district court erroneously dismissed the prisoners' claims of deliberate indifference to medical *needs* on the ground that lethal injection is not specifically a medical *procedure*

Helling v. McKinney, 509 U.S. 35 (1993)

Estelle v. Gamble, 429 U.S. 97, 104 (1976)

VII.

Whether the prisoners bring a viable equal protection claim based on the defendants' practice of carrying out executions during the pendency of stay remedies, in violation of a core provision of the state's execution procedures

Cooey v. Kasich, 801 F. Supp. 2d 623, 652-59 (S.D. Ohio 2011)

In re Ohio Execution Protocol Litig., 840 F. Supp. 2d 1044, 1054-59 (S.D. Ohio 2012)

STATEMENT OF THE CASE

A. Missouri's execution method

This appeal concerns the method of execution announced by the Missouri Department of Corrections in October 2013 and serially modified since that time. *See* App. 228-29, 560-62 (no disclosure of test results or existence of testing); ECF Doc. 163 at 14 (noting changed method of intravenous access); *Bucklew v. Lombardi*, Eighth Circuit Case No. 14-2163, Order of May 20, 2014 at 8-9 (change of IV dyes).¹ The state executes prisoners with a single dose of what it alleges to be pentobarbital, made by an undisclosed and non-FDA-regulated compounding pharmacy that the Department has named to its “execution team,” and composed of unknown ingredients whose sources the Department also hides. Beginning with the execution of Michael Taylor in February 2014, the Department provides no testing data to show that the substance is in fact pentobarbital, or that it is pure, potent, and sterile.

B. The prisoners' evidence of harm

Expert evidence on the use of compounded pentobarbital is undisputed and was attached to the prisoners' second amended complaint. App. 233-82, 290-91,

¹This case began when the prisoners brought suit in the Circuit Court of Cole County, Missouri, against a propofol-based method of execution that the Department of Corrections announced in 2012. ECF Doc. 1. That method, and numerous intervening methods which preceded the current one are not at issue in this appeal.

519-22. Unregulated by the FDA and of unknown origin, compounded pentobarbital presents numerous hazards that create a “substantial risk of serious, unnecessary and substantial harm and mental anguish,” according to pharmacology expert Dr. Larry D. Sasich. App. 270. These hazards include sub-potency or super-potency; contamination from toxins, allergens, or particles; and burning or a pulmonary embolism resulting from failure to reach and maintain the proper pH. App. 259-66. Anesthesiologist Dr. Mark Heath agrees, concluding that Missouri’s protocol is “replete with flaws that present a substantial risk of causing severe and unacceptable levels of pain and suffering during the execution.” App. 236.

What is more, the Department’s practice has materially worsened during the course of the litigation. Earlier, the Department assured the district court that it tests its drugs to be sure they are safe, pure, and effective, so that the prisoners did not need to know the source of the drugs. *See* ECF Docs. 187-12, 191 at 1, 191-1, 212 at 3, 290-5, 290-6, 290-11, 290-13, 290 at 8. The Department made those same assurances to this Court when it sought mandamus relief from the district court’s discovery orders:

Because the chemical tests within the proper ranges, it does not matter who made it. Additionally, the Director will not use a chemical that fails a lab test.

In re Lombardi, Eighth Cir. Case No. 13-3699, Petition for Writ of Mandamus

(Dec. 13, 2013), at 16; *see also* Motion for stay of district court orders (Dec. 27, 2013), at 5 (“The name or the identifying information of whether the pharmacist is part of a national chain, a local pharmacy, or something in between, does not matter when the Court knows the end-product was potent, pure, sterile and worked effectively.”).

But the Department has since refused to disclose any test results, and it successfully resisted all discovery of whether it even tests the drugs at all. *See* Depo of Matthew Briesacher (Mar. 21, 2014), at 43-44, 72-73; App. 560-61 (motion for protective order); App. 642-43, 651 (opposition); Add. 24. The Court is left, then, with the Department’s say-so that the drugs are what it says they are, coupled with its argument that the prisoners are speculating without benefit of the very information that the Department refuses to provide. ECF Doc. 196 at 1 (district court noting “Catch-22” when denying stay to Allen Nicklasson).

C. Relevant procedural history

Some two months after the Department announced its pentobarbital protocol and named its supplier a secret member of the “execution team” under Mo. Rev. Stat. § 546.720.2, the district court ordered a limited disclosure of the Department’s pharmacy, testing laboratory, and prescribing physician. ECF Docs. 203-05; App. 33. This Court eventually vacated that order, reasoning that an Eighth Amendment claim could not go forward under *Baze v. Rees*, 553 U.S. 35

(2008), without the plaintiffs proposing an alternative method of execution, that the prisoners' *ex post facto* claim failed as a matter of law, and that the pharmacy's and laboratory's identities were not relevant to the claims that remained. *In re Lombardi*, 741 F.3d 888, 895-97 (8th Cir. 2014) (en banc) ("*Lombardi I*").

The Court clarified its ruling on rehearing. It distinguished *Hill v. McDonough*, 547 U.S. 573 (2006), and the Supreme Court's holding that there is "no specific pleading requirement that a prisoner must identify an alternative, authorized method of execution to proceed in a § 1983 action." *In re Lombardi*, 741 F.3d 903, 905 (8th Cir. 2014) (en banc) ("*Lombardi II*"), quoting *Hill*, 547 U.S. at 582. *Hill* differed from the present case, the Court concluded, because the prisoner in *Hill* conceded that "other methods of lethal injection the Department could choose to use would be constitutional," and alleged "that the challenged procedure presents a risk of pain the State can avoid while still being able to enforce the sentence ordering a lethal injection." *Id.* The Court pointed out that the *Zink* prisoners included no such allegations in their complaint. *Id.*

Appellants thereafter amended their complaint to include the language from *Hill*. App. 117, 202. They also asserted nine additional claims, several of which are at issue in this appeal.² App. 117-200, 202-21. The district court dismissed

²The prisoners do not appeal the district court's rulings on their claims of medical malpractice, intentional infliction of emotional distress, separation of state powers, or the Missouri Administrative Procedure Act concerning Missouri's or

these claims in two separate orders. Add. 1-26. The first order dismissed all claims other than the one under the Eighth Amendment. Add. 1-24. On that claim, the court ruled that the prisoners showed a sufficient risk of harm to proceed. Add. 8. Nevertheless, the court reasoned that the prisoners lack a viable Eighth Amendment claim without having pleaded a specific alternative method that is “reasonably available” and “less likely to create a substantial risk of harm.” Add. 9-10.

The court deferred its ruling on the claim in order to allow the prisoners to plead a specific alternative, which they declined to do. Add. 10; App. 736-38. They explained that *Baze* does not require a prisoner to specifically plead an alternative method, that the complaint’s language from *Hill* made their claim sufficient under *Lombardi II*, and that they could not specify a “feasible” and “readily implemented” alternative under *Baze* without discovery of the Department’s attempts to obtain other lethal injection drugs. App. 736-38. The district court then dismissed the Eighth Amendment claim and issued its final order and judgment on May 16, 2014. Add. 25-26; App. 744. This appeal follows.

Oklahoma’s pharmacy statutes and regulations. *See* Add. 111-16, 22.

SUMMARY OF ARGUMENT

The Eighth Amendment – State officials seek to execute the appellants with an unregulated compounded drug, from an undisclosed supplier, made of unknown ingredients, and through unknown processes. The district court ruled that the plaintiffs described sufficient evidence of harm for an Eighth Amendment violation, Add. 8, and indeed, the unrefuted expert reports attached to the complaint describe a “substantial risk of serious, unnecessary and substantial harm and mental anguish,” and a “substantial risk of ... severe and unacceptable levels of pain and suffering.” App. 236, 270.

The district court dismissed the claim solely because the prisoners did not plead a specific and “readily available” alternative way for the state to kill them, despite the fact that they could not do so without the aid of discovery into the state’s pursuit of “available” drugs and suppliers. Add. 8-10, 25-26. That ruling is error. The pleading requirement imposed by the district court conflicts with this Court’s ruling on rehearing in *In re Lombardi*, 741 F.3d 903, 905 (8th Cir. 2014) (en banc), which acknowledged the Supreme Court’s holding that there is “no specific pleading requirement that a prisoner must identify an alternative, authorized method of execution to proceed in a § 1983 action.” *Id.*, quoting *Hill v. McDonough*, 547 U.S. 573, 582 (2006). It conflicts with the plain language of the Supreme Court’s opinions in *Hill* as well as *Jones v. Bock*, 549 U.S. 199, 213

(2007). It is unreasonable in light of the district court’s ruling, within the same order, terminating all discovery and thereby disabling the prisoners from discovering what pharmaceuticals and devices are “reasonably available” to the Missouri Department of Corrections. Add. 9-10, 24.

More importantly, the ruling below conflicts with the Supreme Court’s entry of a stay in *Bucklew v. Lombardi*, 134 S. Ct. 2333 (2014). The Court in *Bucklew* issued a stay despite the state’s insistence that it may execute Russell Bucklew because he, too, failed to propose a “specific, feasible, more humane method of execution.” App. 807-10. A stay of execution requires a “significant possibility of success on the merits,” *Hill*, 547 U.S. at 584, and injunctive relief from the Supreme Court pending litigation of an appeal requires the applicant to show that “the legal rights at issue are indisputably clear.” *Turner Broadcasting System v. FCC*, 507 U.S. 1301, 1303 (1993) (Rehnquist, C.J., in chambers). A stay could not have issued if the district court’s view were the governing law on the need for a prisoner to plead an alternative execution method. The prisoners are entitled to prosecute their suit, and the dismissal must be vacated.

The First Amendment – The First Amendment requires the government to disclose information concerning matters that have historically been made public, where the suppression of that information burdens the public’s rights of free expression and access to the courts. *Press-Enterprise Co. v. Superior Court*, 478

U.S. 1, 10-13 (1986). The requirement extends to information regarding executions, in light of Missouri's requirement that executions be witnessed by members of the public. *California First Amendment Coalition v. Woodford*, 299 F.3d 868, 877 (9th Cir. 2002). The First Amendment requires disclosure of the identities of the compounding pharmacy and suppliers of the raw materials for the drug.

The Missouri Administrative Procedure Act – There is no question that the state's method of execution violates federal statutes that exist to protect the end-users of compounded pharmaceuticals and other regulated drugs, including the Drug Quality and Security Act, as well as the prescription requirements of the Food, Drug and Cosmetic Act and the Controlled Substances Act. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (“core” purpose of FDCA is to ensure that every regulated drug is “safe and effective for its intended use”).

The district court dismissed this claim, ruling that the statutes do not confer a private right of action. Add. 21-22. But the prisoners do not sue directly under these statutes. Rather, the defendants' violation of these laws is an element of the prisoners' claim under the Missouri Administrative Procedure Act, which permits injunctive relief when an agency's decision or policy is “unconstitutional, unlawful, unreasonable, arbitrary, or capricious or involves an abuse of discretion.” Mo. Rev. Stat. § 536.150.1; *see also Strong v. American Cyanamid*

Co., 261 S.W.3d 493, 516-17 (Mo. Ct. App. 2007) (tort plaintiffs may rely on federal regulatory requirements, including the FDCA, to establish the “standard of care” in product liability actions).

Ex post facto – Contrary to the district court’s ruling, the prisoners do not need to demonstrate an Eighth Amendment violation in order to show a “significant risk of an increased punishment.” *Williams v. Hobbs*, 658 F.3d 842, 848 (8th Cir. 2011), quoting *Garner v. Jones*, 529 U.S. 244, 255 (2000). The evidence attached to the prisoners’ complaint shows that the defendants have increased the risk of painful executions by abandoning their use of FDA-approved pharmaceuticals in favor of unregulated compounded drugs. App. 91-111, 251-59. The district court dismissed the claim, reasoning that defendant Lombardi has statutory discretion to determine the method of execution. Add. 11, citing *In re Lombardi*, 741 F.3d 888, 896-97 (8th Cir. 2004) (en banc). But Mr. Lombardi does not have boundless discretion to change the method. In particular, he does not have the discretion to violate federal law, which defendants are doing by making and administering a compounded drug that is “essentially a copy” of an FDA-approved drug, and by prescribing it without “a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 U.S.C. § 353a(a); 21 U.S.C. § 829(b); 21 U.S.C. § 353(b); 21 C.F.R. § 1306.04(a).

Due process – When state conduct affects a citizens’ rights, the citizen is entitled to notice of what the government intends to do to him or her, as well as the opportunity to be heard at “a meaningful time and in a meaningful manner.” *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972). The district court ruled that there was no due process violation because the prisoners were able to bring a lawsuit, even though they were unable to bring what the district court considered to be a viable Eighth Amendment claim Add. 17-18. The district court’s own reasoning proves that the prisoners were deprived of due process. The prisoners’ inability to obtain material information about the state’s execution method made a viable claim “impossible” rather than merely “more difficult.” Add. 18, quoting *Giarratano v. Johnson*, 521 F.3d 298, 305-06 (4th Cir. 2006).

Deliberate indifference – Likewise erroneous is the district court’s ruling on the Eighth and Fourteenth Amendment claim that the defendants are acting with “deliberate indifference” to the prisoners’ serious medical needs. The court reasoned that a lethal injection is not a medical procedure. Add. 12. Nevertheless, state actors may be deliberately indifferent to medical needs whether or not they are providing medical care. *E.g., Helling v. McKinney*, 509 U.S. 25, 35 (1993) (viable Eighth Amendment claim because prison officials acted with “deliberate indifference” by exposing a prisoner to second-hand cigarette smoke from his cellmate).

Equal protection – The state’s own procedures forbid officials from carrying out an execution when stay remedies are pending. App. 335-37; ECF Doc. 196 at 10 (order acknowledging violation of protocol). Nevertheless, the defendants executed Joseph Franklin, Allen Nicklasson, and Herbert Smulls when stay remedies were pending in the district court, this Court, and the Supreme Court, respectively. Such protocol deviations violate the Equal Protection Clause, because the prisoners are left without any assurance that the state will execute them in accordance with established and consistent procedures. *Cooey v. Kasich*, 801 F. Supp. 2d 623, 652-59 (S.D. Ohio 2011) (deviation from “core” aspects of written protocol violated equal protection).

The district court ruled that the state’s allowance of pre-execution judicial review is not a “core” provision of its procedures, because it does not involve the administration of lethal chemicals or preparations for that act. Add. 18-19. But no authority so limits “core” procedures. See *In re Ohio Execution Protocol Litig.*, 840 F. Supp. 2d 1044, 1053 (S.D. Ohio 2012) (“core provision” includes requirement that DOC director approve any “non-core” deviations). Written protocols exist in order to provide constitutionally-required safeguards against the infliction of severe pain. *Ringo v. Lombardi*, 706 F. Supp. 2d 952, 962 (W.D. Mo. 2010). The defendants’ conduct thwarts that core purpose of their procedures.

STANDARD OF REVIEW

On appeal from the grant of a motion to dismiss, this Court reviews the district court's ruling de novo. *Riley v. St. Louis County*, 153 F.3d 627, 630 (8th Cir. 1998). The Court applies the same standard as the district court in reviewing the plaintiffs' claims, accepting the factual allegations in the complaint as true. *Id.*; *Cook v. ACS State & Local Solutions*, 663 F.3d 989, 992 (8th Cir. 2011). In order to survive a motion to dismiss, a complaint must allege facts that are sufficient to "state a claim to relief that is plausible on its face." *Walker v. Barrett*, 650 F.3d 1198, 1203 (8th Cir. 2011), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In making that determination, a court must draw all reasonable inferences in favor of the non-moving party. *Palmer v. Ill. Farmers Ins. Co.*, 666 F.3d 1081, 1083 (8th Cir. 2012).

ARGUMENT

- I. The district court, which ruled that the prisoners showed a sufficient risk of severe pain to survive dismissal, erred by dismissing the Eighth Amendment claim solely because the prisoners did not plead an alternative method of execution that is “reasonably available” to the Missouri Department of Corrections.**
- A. Missouri’s method of lethal injection creates a substantial risk of serious harm, and the district court soundly held that the plaintiffs bring a viable Eighth Amendment claim in this respect.**

The prisoners’ claim requires them to show “a substantial risk of serious harm, an objectively intolerable risk of harm that prevents prison officials from pleading that they were subjectively blameless for purposes of the Eighth Amendment.” *Baze v. Rees*, 553 U.S. 35, 50 (2008) (opinion of Roberts, C.J.). The district court correctly ruled that the prisoners “sufficiently plead an Eighth Amendment claim regarding the risk and level of pain that the current execution protocol carries.” Add. 8.

The prisoners plead that the defendants’ use in lethal injections of what they represent to be pentobarbital from an undisclosed compounding pharmacy creates a substantial risk of severe pain. App. 79-117, 201-02. Compounding pharmacies are not subject to the government regulation on which Americans rely for the identity, purity, potency, and efficacy of the medications they take—and on which experts and courts have relied in rendering opinions and making judgments about the substances which the defendants have used in past lethal injection litigation.

App. 91-111. Among other problems, reputable vendors of pentobarbital will not sell the drug to the Department of Corrections, unregulated compounded drugs involve precursor chemicals from unknown and unregulated suppliers, and compounding pharmacies lack the institutional competence to test either the precursor chemicals or the product they tender to their customers. App. 97-100.

Attached to and included within the complaint are analyses from pharmacology expert Larry D. Sasich and anesthesiologist Mark J.S. Heath. Dr. Sasich explains that compounded drugs are unreliable because they are largely unregulated. App. 251-54. Compounding pharmacies represent “an emerging, substandard drug industry responsible for making large quantities of unregulated, unpredictable and potentially unsafe drugs.” App. 253. The drugs they make often contain counterfeit or substandard ingredients, and drug compounders often use poor practices; as a result, the process of compounding “often results in drugs which are contaminated, sub-potent or super-potent, or which do not have the strength, quality or purity … required for the safe and effective treatment of patients.” App. 254.

Reputable suppliers of pharmaceutical ingredients generally sell directly only to FDA-approved manufacturers of finished products. App. 258. That leaves compounding pharmacies to depend on the unregulated “grey market” in which ingredients may come from China, India, or other countries that do not reliably

inspect pharmaceutical ingredients; the drugs may not even be what they purport to be, and it is all but impossible to trace the active ingredient to its original manufacturer in order to verify its quality. App. 257-59. In light of these hazards, “The potential harm associated with the use of such contaminated or sub-potent drugs is extremely high.” App. 254.

Dr. Sasich outlines four specific hazards from the use of compounded pentobarbital in executions. First, there is a “substantial risk” that the drug may be sub-potent or super-potent, either from (a) the fact that Missouri’s protocol specifies no means of adjusting the measurements of the chemical to account for the drug’s hygroscopic (water-absorbing) nature, (b) chemical degradation caused by impurities or contamination, (c) a compounding error, or (d) the possibility that the defendants’ drug is not actually pentobarbital. App. 259, 263-66. Sub-potent pentobarbital risks “acute but not lethal intoxication,” “life-threatening but not fatal respiratory depression and corollary organ damage (including brain damage), and/or paradoxical central nervous excitation.” App. 265. Super-potent pentobarbital, meanwhile, may result in “suffocation and gasping for breath, before the loss of consciousness.” App. 266.

A second problem Dr. Sasich identifies is the danger that compounded pentobarbital will be contaminated with dangerous allergens, toxins, bacteria, or fungus—any of which could induce severe allergic or blood reactions that are

“highly unpredictable, rapidly evolving and potentially painful and agonizing.”

App. 261-63. A third danger arises from particle contamination. The compounded pentobarbital may contain foreign particles that will either contaminate the solution or precipitate out of it, creating a “substantial risk of pain and suffering” on injection, as well as a risk of pulmonary embolism. App. 262-64. Fourth and finally, Dr. Sasich states that the dosage form of the drug may fail to reach or maintain the proper pH, which risks burning on injection, the precipitation of solid particles that could cause a pulmonary embolism, or the multiplication of bacteria and fungus that may “create instability and/or incompatibility with human blood.”

App. 264.

All told, Dr. Sasich concludes, compounded pentobarbital creates a **“substantial risk of serious, unnecessary and substantial harm and mental anguish.”** App. 270 (emphasis added). Anesthesiologist Dr. Heath agrees. He states that sub-potent pentobarbital may severely disable the prisoner without actually killing him. It carries a risk that the prisoner “will be unconscious for an extended period of time while breathing inadequately, before waking up in a permanently brain-damaged state.” App. 234. Dr. Heath concludes that Missouri’s protocol is “replete with flaws that present a **substantial risk of causing severe and unacceptable levels of pain and suffering** during the execution.” App. 236 (emphasis added).

To make matters worse, the defendants are administering expired drugs. Dr. Sasich explains that United States Pharmacopeia Chapter <797> defines the “Beyond Use Date” (BUD) as the date or time after which a compounded sterile preparation should not be administered, stored, or transported. Chapter <797> of the USP assigns BUDs for drugs compounded from non-sterile Active Pharmaceutical Ingredients (High Risk Compounding). If the drug is stored at room temperature, the BUD is 24 hours; if refrigerated, 3 days, and if frozen, 45 days. App. 519-20. Based on laboratory reports disclosed by the defendants—which they ceased disclosing after their first three pentobarbital executions—the drugs used in Joseph Franklin’s execution were stored at room temperature and were compounded sixteen days before the execution, and the defendants administered an expired drug. App. 521. A similar analysis governs the drug with which Allen Nicklasson was executed. App. 521-22. Dr. Sasich described the state’s practices as a “very troubling deviation from USP standards,” which carries a “very high risk that the compounded drug will degrade or allow for more rapid growth of bacteria.” App. 104. Improper storage creates “a very substantial, even grave, risk that the prisoner will suffer severe pain and/or an immediate severe allergic reaction.” App. 105.

B. The complaint's lack of a specific alternative method of execution that is "reasonably available" to the Missouri Department of Corrections cannot justify dismissal.

The district court dismissed the Eighth Amendment claim solely because the complaint did not recommend an alternative method that is "reasonably available" to the defendants and "less likely to create a substantial risk of harm." Add. 8-10, 25-26. The court relied on this Court's rulings as support for the alternative-method requirement that it imposed. *See In re Lombardi*, 741 F.3d 888, 895-96 (8th Cir. 2014) (en banc); *In re Lombardi*, 741 F.3d 903, 905 (8th Cir. 2014).

But that requirement cannot and will not persist in the manner applied by the district court. It has been superseded by intervening authority from the Supreme Court, which stayed Russell Bucklew's execution despite Mr. Bucklew's failure to specify an alternative to Missouri's method. *Bucklew v. Lombardi*, 134 S. Ct. 2333 (2014). It conflicts with this Court's ruling in *Lombardi II*, which, in order to reconcile the alternative-method requirement with earlier Supreme Court precedent, holds that it suffices if the prisoner's pleading alleges that "other methods of lethal injection the Department could choose to use would be constitutional," and that "the challenged procedure presents a risk of pain the State can avoid while still being able to enforce the sentence ordering a lethal injection." 741 F.3d at 905, quoting *Hill v. McDonough*, 547 U.S. 573, 580-81 (2006). In any event, the Court should overrule *Lombardi* because it conflicts with *Hill*, misreads

Baze, and is unworkable to the point of disabling any prisoner from challenging a state’s method of execution under the Eighth Amendment.

1. The Supreme Court’s grant of a stay in *Bucklew* repudiates the rule of *Lombardi*.

Russell Bucklew did not propose an alternative method of execution even though the state insisted that he must. A stay of execution requires a prisoner to show, among other things, a “significant possibility of success on the merits.” *Hill v. McDonough*, 547 U.S. 573, 584 (2006). Beyond the requirements for a stay of execution, the Supreme Court issued a stay pending Mr. Bucklew’s appeal in this Court. That remedy requires the applicant to show that “the legal rights at issue are indisputably clear.” *Turner Broadcasting System v. FCC*, 507 U.S. 1301, 1303 (1993) (Rehnquist, C.J., in chambers). These showings exceed the more modest showing of a “plausible” claim required to survive a motion to dismiss. *Ringo v. Lombardi*, 706 F. Supp. 2d 952, 961 (W.D. Mo. 2010); *Ringo v. Lombardi*, No. 09-4095-CV-C-NKL, 2010 WL 4103201, at *1 (W.D. Mo. Oct. 18, 2010).

Prominently featured before the Supreme Court was the issue of whether Mr. Bucklew must propose an alternative method of execution in order to bring a viable Eighth Amendment claim. The district court answered that question affirmatively, and the state argued the point at length when opposing a stay. App. 807-10. The state defended the district court’s ruling that Mr. Bucklew’s complaint “did not allege or even acknowledge a feasible and more humane

alternative method of execution,” and therefore, that Mr. Bucklew “failed to allege sufficiently an Eighth Amendment claim under *Baze*.” App. 807. The state went on to criticize various modifications recommended by Mr. Bucklew, such as his proposal that the Department allow a non-execution team physician to be present in order to revive Mr. Bucklew during a botched execution, because the proposals “are not really changes in the method of execution.” App. 808-10.

Mr. Bucklew strenuously disagreed. He argued *Baze* does not require the prisoner to propose an alternative means of his demise, particularly in light of the Court’s earlier rulings in *Hill v. McDonough*, 547 U.S. 573, 582 (2006), and *Jones v. Bock*, 549 U.S. 199, 213 (2007), both of which disclaimed such a pleading requirement. App. 776-79, 821. He argued that he could not allege an alternative method without the ability to discover undisclosed facts “regarding the drugs to be used, their origin, and the ingredients used in compounding them.” App. 765, 794, 821-22. And he argued that the alternative-method requirement creates an untenable conflict of interest between the prisoner and counsel, who, in order to fulfill this requirement, must advocate for the client’s death and lend his or her wits to bring it about in a particular manner. App. 781-83, 794.

If a prisoner were required to plead an alternative method in order to survive a motion to dismiss, then Mr. Bucklew could not have shown a “significant possibility of success on the merits”—much less that “the legal rights at issue are

indisputably clear”—without specifying such an alternative himself. The *Bucklew* ruling casts grave doubt on this Court’s precedent. *In re Lombardi*, 741 F.3d 888, 896 (8th Cir. 2014) (en banc), states that an Eighth Amendment claim requires either a “a plausible allegation of a feasible and more humane alternative method of execution” or a “purposeful design by the State to inflict unnecessary pain.” Russell Bucklew would have been executed on May 21 if that were the law. This Court’s precedent is not binding when, as here, “an intervening expression of the Supreme Court is inconsistent with those previous opinions.” *Young v. Hayes*, 218 F.3d 850, 853 (8th Cir. 2000).

2. The *Lombardi* rehearing order clarifies that the complaint itself need not specify an alternative execution method.

The Court clarified *Lombardi* on rehearing. See *In re Lombardi*, 741 F.3d 903 (8th Cir. 2014) (en banc). It rejected the prisoners’ argument that its reading of *Baze* conflicted with *Jones v. Bock*, 549 U.S. 199, 213 (2007), and *Hill v. McDonough*, 547 U.S. 573, 582 (2006). Confronted with the facial conflict between the en banc opinion requiring that a viable claim propose an alternative method, on the one hand, and the Supreme Court’s ruling in *Hill*, on the other, the *Lombardi* court attempted to harmonize the two rulings as follows:

In *Hill*, however, the plaintiff conceded that “other methods of lethal injection the Department could choose to use would be constitutional,” [547 U.S.] at 580, and he alleged “that the challenged procedure presents a risk of pain the State can avoid while still being able to enforce the sentence ordering a lethal injection.” *Id.* at 581. The

plaintiffs in this case did not make such an allegation in the amended complaint. We therefore concluded that they failed to state a claim by failing to allege even the elements of an Eighth Amendment claim as defined in *Baze*. We were not required to address whether alleging that the current method of execution creates a substantial risk of harm when compared to known and available alternatives, without specifying an alternative, would be sufficient to state a claim in light of *Hill* and *Baze*. *Cf. Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Lombardi II, 741 F.3d at 905.

Without admitting the underlying premise of the two *Lombardi* opinions, the prisoner's second amended complaint supplied the asserted omission. It included the *Hill* language whose absence this Court held to be dispositive. The prisoners alleged that "the challenged procedure presents a risk of pain the State can avoid while still being able to enforce the sentence ordering a lethal injection." App. 117, 202. They also "concede[d] that other methods of lethal injection the Department could choose to use would be constitutional." App. 202. The plaintiffs therefore brought their action within the fact-pattern of *Hill* in the respect that the en banc order harmonized the Court's opinion with *Hill*.

The district court's ruling to the contrary is erroneous. Pointing to the en banc order's citation of *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the district court reasoned that *Iqbal* itself requires the prisoner to specify a reasonably available alternative that is less likely to create a substantial risk of harm, and that the *Hill* language is a mere "naked assertion" that does not create a "plausible" claim for relief. Add. 9-10. But this Court said no such thing when it tried to harmonize

Baze and *Hill*, and indeed, the Court could not harmonize *Baze* and *Hill* by requiring a prisoner to allege anything more than Mr. Hill himself did. If *Iqbal* required a prisoner to plead an alternative method, then this Court would have said so.

Moreover, if the district court were correct, one would also expect the Supreme Court in *Baze* to have clarified that *Hill* and *Jones* were overruled by the *Iqbal* principle announced in *Bell v. Twombly*, 550 U.S. 544 (2007). The opinion in *Twombly* preceded *Baze* by eleven months. Like *Iqbal*, the ruling in *Twombly* disapproved “formulaic recitations of the elements of a cause of action,” and “naked assertions” devoid of further factual enhancement. 550 U.S. at 555, 557. These principles already governed pleading at the time of *Baze*. If indeed the *Twombly/Iqbal* principle overruled the unanimous opinions in *Hill* and *Jones* by requiring a prisoner’s complaint to specify an alternative method of execution, then the Court in *Baze* would have said so.

3. The district court wrongly required the prisoners to suggest an alternative method without the benefit of discovery to ascertain what other pharmaceuticals or means of execution are “reasonably available” to the Missouri Department of Corrections.

The district court’s approach is as unworkable in practice as it is unsound in precedent. The prisoners cannot propose a “reasonably available” alternative method without full and fair discovery into the Department’s efforts to identify,

select, procure, and test execution drugs. The prisoners cannot show that an alternative method is “feasible” and “readily implemented,” *Baze*, 553 U.S. at 52, without knowing what efforts the defendants have attempted, even as the defendants themselves insist that suppliers are hesitant to furnish them with lethal injection drugs, so that they cannot obtain FDA-regulated drugs from lawful suppliers of them. ECF Doc. 189-1 (Lombardi Aff.) ¶¶ 5-6, 10. The defendants resisted any and all discovery of their present or previous suppliers, and they refused to comply with any such discovery after the *Lombardi* rulings. App. 560-61, 643, 650-51; Depo. of Matthew Briesacher (Mar. 21, 2014), at 43-44, 72-73.

The district court’s order stayed all discovery while purporting to give the prisoners a chance to recommend a different execution method. Add. 24. The order prevented compliance with its own directive, because the prisoners cannot discover specific information that is uniquely and peculiarly available to the state. The practical effect is to disable any Eighth Amendment claim targeting any method of lethal injection, unless the prisoner somehow knows how and where his executioner may readily obtain the instruments of his death—and in a regime where that very information is kept secret by the executioners, their supervisors, and their attorneys.

The state is likely to argue, as it has before, that discovery requires a plaintiff to plead a sufficient claim in the first instance, or that “the discovery

process exists to support a viable claim.” Opposition to Winfield Motion for Stay of Execution (filed June 6, 2014), at 8. Otherwise stated, a prisoner must somehow have foreknowledge into the state’s abilities to procure particular drugs from particular suppliers, and must then propose a “reasonably available” method that diminishes the risk of severe pain. But prisoners are no more clairvoyant than any other litigant. The state’s rule, as imposed by the district court, effectively disables any Eighth Amendment lethal injection claim.

4. Alternatively, the Court should overrule *Lombardi* because it conflicts with binding Supreme Court authority.

Less than one year before *Baze v. Rees*, 553 U.S. 35 (2008), the Supreme Court remarked as follows in *Jones v. Bock*, 549 U.S. 199, 213 (2007):

In *Hill v. McDonough*, 547 U.S. 573 (2006), we unanimously rejected a proposal that §1983 suits challenging a method of execution must identify an acceptable alternative.

The opinion in *Baze* does not remotely suggest that the Court was departing from *Jones* and *Hill*, or that the Court was creating a new pleading or proof requirement. The Court instead disapproved any test that compares one method to another, which would “transform courts into boards of inquiry charged with determining ‘best practices’ for executions[.]” *Baze*, 553 U.S. at 51. Indeed, *Baze* did not distinguish or even cite *Jones* or *Hill*.

Lombardi not only conflicts with *Jones* and *Hill*, but also misreads *Baze* itself. See *Lombardi I*, 741 F.3d at 895-96 (analyzing plurality and concurring

opinions). The Court in *Baze* was confronted with the specific claim that Kentucky's execution protocol violated the Eighth Amendment because the state could easily change to a one-barbiturate method or at least discontinue the use of the paralytic agent pancuronium bromide. 553 U.S. at 56-57. That specific claim required the prisoner to show that the proposed alternative was feasible, available, and likely to reduce a significant risk of pain. *Id.* at 52, 61. *Baze* simply addressed the claim before the Court. By inferring from *Baze* an over-arching rule that the prisoner must always propose an alternative, the *Lombardi* opinion divorces the *Baze* holding from its context—all the while forcing attorneys to advocate for the demise of their clients. *See* Mo. Sup. Ct. R. 4-1.2(a) (duty of adherence to client's objectives about the representation); Mo. Sup. Ct. R. 4-1.3 (duty of diligence); Mo. Sup. Ct. R. 4-1.7(a) (conflict of interest). *Lombardi* should be overruled.

II. The First Amendment entitles the prisoners, as members of the public, to know the source and other information concerning the drug that the state will use to execute them.

The prisoners contend that, as members of the public,³ they are entitled under the First Amendment to know the identity of the pharmacy which compounds the chemicals used in executions, and of the suppliers of ingredients used in the compounding process. Dismissing this count, the district court held, first, that “Plaintiffs set forth no binding authority suggesting they have a right to access the otherwise confidential identities of execution team members.” Add. 23. Of course, a complaint need not set forth “binding” or any other authority. It must simply allege facts that “state a claim to relief that is plausible on its face.” *Walker v. Barrett*, 650 F.3d 1198, 1203 (8th Cir. 2011).

To the extent that the district court held that there is no right under the First Amendment to obtain access to information in the possession of governmental agencies, that assertion is incorrect. “[T]he First Amendment guarantees the public—and the press—a qualified right of access to governmental proceedings.” *California First Amendment Coalition v. Woodford*, 299 F.3d 868, 873 (9th Cir. 2002). This is because “a major purpose of that Amendment was to protect the free

³The First Amendment count does not include the word “plaintiffs” in every paragraph. The word “public,” however, is included, and the prisoners are members of the public. *See, e.g., Jackson v. Nixon*, 747 F.3d 537, 542 (8th Cir. 2014) (Prisoners, like other members of the public, have the right not to be coerced to participate in religion).

discussion of governmental affairs.” *Globe Newspaper*, 457 U.S. 596, 604 (1982). In particular, the Supreme Court has recognized that the press has a right of access to criminal trials, *Richmond Newspapers v. Virginia*, 448 U.S. 555, 579-80 (1980); the testimony of child sex offense victims, *Globe Newspaper Co.*, 457 U.S. at 603-11; jury selection, *Press-Enterprise Co. v. Superior Court*, 464 U.S. 501, 505-11 (1984); and preliminary hearings in criminal cases, *Press-Enterprise Co. v. Superior Court*, 478 U.S. 1, 10-13 (1986).

This right extends to documents related to civil as well as criminal proceedings. *Gannett Co. v. DePasquale*, 443 U.S. 368, 386 n.15 (1979) (noting tradition of public access); *Courthouse News Service v. Planet*, 750 F.3d 776, 786 (9th Cir. 2014); *Publicker Indus v. Cohen*, 733 F.2d 1059, 1070 (3d Cir. 1984).

While the First Amendment does not grant an unqualified right to any government document, it does apply where the documents at issue are intrinsically intertwined with a recognized right to access. *California First Amendment Coalition*, 299 F.3d at 876-77 (public enjoys First Amendment right to access executions, including initial procedures that are “inextricably intertwined with the process of putting the condemned inmate to death”).

The public, including the prisoners, has an enforceable right of access to certain government proceedings in the criminal system and records associated with those proceedings. *Press-Enterprise II*, 478 U.S. at 8-14; *Press-Enterprise I*, 464

U.S. at 510-11; *Globe Newspaper*, 457 U.S. at 603-11; *Richmond Newspapers*, 448 U.S. at 579. The right of access attaches specifically where (a) proceedings or records are historically open to the public and (b) public access to the specific proceedings or records plays a significant positive role in the functioning of government. *Press-Enterprise II*, 478 U.S. at 8, citing *Globe Newspaper*, 457 U.S. at 604.

Prior to October 18, 2013, Missouri made available to the public and to prisoners facing execution the identities of suppliers of drugs to be used. *Compare* App. 228 (current protocol naming suppliers to confidential “execution team”), *with* ECF Doc. 1, Heath Aff. Ex. 2 at 1 (protocol of May 15, 2012) (“the execution team consists of medical personnel and department employees”), ECF Doc. 124-4 at 1 (same, protocol of Aug. 1, 2013), ECF Doc. 139-1 at 1 (same, protocol of Sept. 24, 2013). That changed with the protocol now at issue, and the Director of the Department of Corrections invoked a “state secrets” privilege to shield the identity of the Department’s supplier as well as any documents that could lead to discovery of the supplier. App. 560-61; ECF Doc. 189-1 at 2.

Not only has this information historically been available to prisoners and the rest of the public, but the right of public access to executions has long been recognized. Under Missouri law, at least eight members of the public must attend each execution. Mo. Rev. Stat. § 546.740; *Rice v. Kempker*, 374 F.3d 675, 678 n. 2

(8th Cir. 2004). And at least one circuit has held that the right of public access to executions is of constitutional dimension. *Id.*; *California First Amendment Coalition*, 299 F.3d at 877. These circumstances satisfy the first requirement of the *Press-Enterprise* test. Moreover, public access to this information would have a significant positive effect. As recent events in Arizona, Ohio, and Oklahoma demonstrate, *see* Section V.B., below (on due process claim), secrecy in the preparation of execution chemicals leads at least to the inference that the state lacks adequate safeguards to ensure that executions comport with the Eighth Amendment.

Because this is a content-based restriction on public access to information, it is subject to strict scrutiny. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011). In *Sorrell*, a Vermont statute restricted the disclosure of pharmacy records that revealed individual doctors' prescribing practices. As a result, pharmaceutical manufacturers were denied the use of this information to market their products. That restriction was unconstitutional: "Vermont's law does not simply have an effect on speech, but is directed at certain content and is aimed at particular speakers." *Id.* at 2665.

The district court also held that a First Amendment claim could not be sustained because the prisoners were not asserting that they were unable to disseminate information in their possession, but rather sought information in the

possession of the government, citing *Los Angeles Police Dept. v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999). Add. 23. But *Sorrell* squarely rejected this distinction: “Vermont further argues that § 4631(d) regulates not speech but simply access to information ... It is true that the respondents here ... do not themselves possess information whose disclosure has been curtailed. That information, however, is in the hands of pharmacies and other private entities.” *Sorrell*, 131 S.Ct. at 2665. In *Los Angeles Police*, the Court in *Sorrell* explained, the information in question was police arrest records, not records of transactions between the government and private parties. Here, however, as in *Sorrell*, the information is in the hands of private parties. Thus, once the restricted information is communicated to the government, the First Amendment’s protection is available to the prisoners. Moreover, as the Court explained,

This Court has held that the creation and dissemination of information are speech within the meaning of the First Amendment ... Facts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs. There is thus a strong argument that prescriber-identifying information is speech for First Amendment purposes.

131 S. Ct. at 2667.

The appellees may rely on *Wellons v. Commissioner*, — F.3d —, No. 14-12663-P, 2014 WL 2748316 (11th Cir. Jun. 17, 2014). *Wellons* relies on *Lewis v. Casey*, 518 U.S. 343 (1996), to reject the prisoners’ due-process-based right of access to information about execution drugs. 2014 WL 2748316, at *6 (holding

that due process requires only that prisoners be allowed to litigate claims, not that they be allowed to discover the basis for bringing them). But the court did not separately explain why it was rejecting Mr. Wellons' First Amendment claim. *Id.* And even then, the ruling simply upholds the denial of a stay of execution in the hours before Mr. Wellons' death. *Id.* That inquiry differs from the question of whether a prisoner brings a plausible claim that survives dismissal. *Ringo v. Lombardi*, 706 F. Supp. 2d 952, 961 (W.D. Mo. 2010)

Neither are the defendants assisted by the Supreme Court's recent order in *Ryan v. Wood*, — S. Ct. —, No. 14A-82, 2014 WL 3600362 (U.S. Jul. 22, 2014). That decision, as with *Wellons*, remarked that the district court did not abuse its discretion in denying injunctive relief to the prisoner. In *Wood v. Ryan*, — F.3d —, No. 14-16310, 2014 WL 3563348 (9th Cir. Jul. 19, 2014), the Ninth Circuit held that Mr. Wood was entitled to a preliminary injunction staying his execution until he was provided information about the drugs to be used. The court held that executions are historically open events, and that "independent public scrutiny ... plays a significant role in the proper functioning of capital punishment." *Id.* at *7.

The court continued:

Given the law in *California First Amendment Coalition*, and the factual backdrop of the past six months in particular, more information about the drugs used in lethal injections can help an alert public make better informed decisions about the changing standards of decency in this country surrounding lethal injection. Knowing the source and manufacturer of the drugs, along with the lot numbers and NDCs, allows

the public to discern whether state corrections departments are using safe and reliable drug manufacturers. Similarly, knowing the specific qualifications of those who will perform the execution will give the public more confidence than a state’s generic assurance that executions will be administered safely and pursuant to certain qualifications and standards.

Id. at *8.

The Supreme Court reversed the Ninth Circuit’s grant of a preliminary injunction, but in so doing, it did not reject the Ninth Circuit’s reasoning on the merits. It simply held that Mr. Wood had not shown an abuse of discretion by the district court that denied a preliminary injunction, *Wood*, 2014 WL 3600362, and indeed, the dissenting Ninth Circuit judges criticized the “mismatch” between the public’s right to access and the individual prisoner’s stay of execution. *See Wood v. Ryan*, 2014 WL 3563348, at *22-*23 (Bybee, J., dissenting); *see also Wood v. Ryan*, No. 14-16310 (9th Cir. Jul. 21, 2014), Docket ID 9175804, at 4 & n.6 (Callahan, J., dissenting from the denial of rehearing).

Here, however, the standard of review is different. The prisoners must merely show that their pleadings state a plausible constitutional claim, not that they have a likelihood of success. And, unlike Mr. Wood, they are entitled to have the facts and law construed in their favor. Those facts are even more egregious than discussed in the Ninth Circuit’s opinion, which referred to “several flawed executions this year, including two in Oklahoma, and one in Ohio.” 2014 WL 3563348 at *7. But this Court now has before it the troubling execution of Mr.

Wood himself, who spent almost two hours gasping for breath before he died.⁴

The prisoners have asserted a First Amendment right to the information at issue here. The defendants have not shown a compelling state interest to restrict that information based on the pharmacy's membership on the "execution team" or any "state secrets" privilege. They speculate that they would have difficulty in obtaining compounded pentobarbital if they were forced to reveal the source. Likewise, they speculate that the providers would be subject to physical harm. But they present no evidence to support either premise, and no authority to suggest that the government has a compelling interest to shield information that might lead the public to oppose the state's actions and those of its accomplices. The prisoners are entitled to proceed on their claim.

⁴Michael Muskal, *How did Arizona execution go wrong*, Los Angeles Times, July 24, 2014.

III. The district court erroneously dismissed the prisoners' claims that Missouri's execution method violates the Drug Quality and Security Act, the Food, Drug and Cosmetic Act, and the Controlled Substances Act, for which the Missouri Administrative Procedure Act provides a private right of action when an agency's actions are unlawful.

The Missouri Administrative Procedure Act allows a party aggrieved by a state agency's decision or policy to obtain injunctive relief when the decision is "unconstitutional, **unlawful**, unreasonable, arbitrary, or capricious or involves an abuse of discretion." Mo. Rev. Stat. § 536.150.1 (emphasis added). The Department of Corrections' method of execution is "unlawful" in numerous respects. First, the Drug Quality and Security Act forbids the compounding of "essentially a copy" of an FDA-approved drug, which is precisely what the defendants are doing when they compound and administer what they purport to be the pharmacological equivalent of FDA-approved pentobarbital. *See* Pub. L. No. 113-54, 127 Stat. 587 (Nov. 27, 2013), § 102(a) (modifying scope of FDCA § 505), codified at 21 U.S.C. § 353a(a). The Defendants' compounded "copy" of an FDA-approved drug constitutes an illegal and unapproved "new drug" under 21 U.S.C. § 355. *See* 21 U.S.C. § 353a(a) (specifying exceptions to section 355 when compounded drugs meet specific requirements).

Second, the Food, Drug and Cosmetic Act and the Controlled Substances Act require a valid medical prescription for the dispensing and administration of pentobarbital, which is a Schedule II or III controlled substance. *See* 21 U.S.C. §

829(b); 21 U.S.C. § 353(b); 21 C.F.R. § 1308.13(c)(1). A valid prescription requires “a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a); *United States v. Smith*, 573 F.3d 639, 646, 650-52 (8th Cir. 2009); *United States v. Nazir*, 211 F. Supp. 2d 1372, 1374-75 (S.D. Fla. 2002). But the prisoners for whom the prescriptions for execution drugs are written have no medical need for compounded pentobarbital; the only “need” for the compounded drug arises from the fact that the defendants want to use it for executions and claim that they cannot obtain the real drug from legitimate channels. Indeed, the physician who issues prescriptions-on-demand does not examine the prisoner, review his records, or have any medical relationship with him. App. 175, 179, 187, 283-84, 446-49.

These statutory violations place the prisoners at risk. A non-FDA approved substance is not reliably potent, pure, and effective, *see* App. 251-55, and therefore, to “copy” an FDA-approved drug is to subject the recipient to an unnecessary risk without any corresponding medical benefit. Neither is the prescription requirement a mere technicality. A prescription reflects a physician’s clinical judgment to use a particular drug for a particular medical purpose. For example, Dr. Sasich explains, a two-year-old transplant patient might require a medicine for which the only FDA-approved form is a pill. App. 249. In such a case, “a tablet’s ingredients may be reformulated into an oral liquid for

administration”—a measure that is life-sustaining based on a doctor’s clinical judgment that the benefits of the medication outweigh the risks of using non-FDA-approved ingredients. *Id.* But no such medical judgment exists in this case to justify the risk of unapproved pharmaceuticals. The prisoners are subjected to grey-market pentobarbital only because the Department of Corrections has found a willing supplier. “Because neither the pharmacist nor the prescribing physician is fulfilling the professional role as the prisoners’ learned intermediary, this non-medically-directed compounding is tantamount to drug counterfeiting,” explains Dr. Sasich. App. 254. “The resulting dosage form is experimental and unpredictable in both composition and with respect to intended and unintended adverse effects.” App. 254-55.

A. The Department of Corrections need not have formulated its policy as part of a “contested case” in order for those aggrieved by the policy to seek review under the MAPA.

The district court fundamentally misapplied Missouri administrative law. It ruled that a party may seek judicial review of an agency decision, but only in a “contested case,” which the court defined as a case in which the agency has held a formal “proceeding” to determine the “legal rights, duties or privileges of any person.” Add. 20, 22. The court ruled that the DOC’s adoption of an execution protocol is not a “contested case,” and therefore, any resulting illegalities are not reviewable under the MAPA. Add. 22.

It is true that the requirement of a formal hearing differentiates a “contested case” and a “non-contested case” under Missouri law. *Kish v. Chilhowee R-IV School Dist.*, 814 S.W.2d 649, 652-53 (Mo. Ct. App. 1991). But nothing requires a “contested case” in order for a court to review the legality of agency action. “In either a contested or a non-contested case the private litigant is entitled to challenge the governmental agency’s decision.” *City of Valley Park v. Armstrong*, 273 S.W.3d 504, 506 (Mo. 2009). “The difference is simply that in a contested case the private litigant must try his or her case before the agency, and judicial review is on the record of that administrative trial, whereas in a non-contested case the private litigant tries his or her case to the court.” *Id.* at 507. The two types of decisions are governed by different statutes, but both allow an aggrieved party to seek injunctive relief when the agency’s decision is unlawful, an abuse of discretion, or arbitrary and capricious. *See Mo. Rev. Stat. § 536.140.2* (contested cases); *Mo. Rev. Stat. § 536.150.1* (noncontested cases). That is what the prisoners did below in their complaint. App. 215-18.

Reviewing matters outside the pleadings, the district court seems to have been confused by the prisoners’ failed effort to persuade the Missouri and Oklahoma Boards of Pharmacy to enforce their state pharmacy laws and regulations, as well as federal law, against the defendants. Add. 20-21. But the prisoners do not seek judicial review of the pharmacy boards’ discretionary non-

enforcement decisions, including the Missouri Board’s determination that it does not have authority to prosecute non-pharmacy entities. Rather, the prisoners seek review of the Department of Corrections’ decision to adopt the current protocol in the first place. That decision is reviewable under the MAPA even though the protocol is not a “rule” subject to notice-and-comment requirements. Under Mo. Rev. Stat. § 536.150.1, a court may determine whether the agency’s decision is “unconstitutional, unlawful, unreasonable, arbitrary, or capricious or involves an abuse of discretion.” Nothing in section 536.150.1 exempts an agency’s policy or decision from review simply because it is not a promulgated “rule” under the MAPA. *E.g., McIntosh v. LaBundy*, 161 S.W.3d 413, 415-17 (Mo. Ct. App. 2005) (exclusion from DOC’s list of approved therapists for sex offenders); *State ex rel. Koster v. Morningland of the Ozarks, LLC*, 384 S.W.3d 346, 349-50 (Mo. Ct. App. 2012) (seizure of cheese by Milk Board); *Cole v. Conservation Commission*, 884 S.W.2d 18, 19-20 (Mo. Ct. App. 1994) (termination of employment).

B. The prisoners have a private right of action through the MAPA, under which the state agency’s violation of federal law is an element of a state-law cause of action.

The district court alternatively reasoned that the prisoners may not “enforce” the FDCA (of which the Drug Quality and Security Act is a part) and CSA because those statutes do not create a private right of action. Add. 21-22. But the prisoners here do not seek to an impermissible “enforcement” of these statutes.

They merely bring a state-law claim that carries the federal violation as an element of the claim. That is both unremarkable and allowable under state as well as federal law. *E.g., Strong v. American Cyanamid Co.*, 261 S.W.3d 493, 516-17 (Mo. Ct. App. 2007) (holding that tort plaintiffs may rely on federal regulatory requirements, including the FDCA, to establish the “standard of care” in product liability actions), overruled in part on other grounds by *Badahman v. Catering St. Louis*, 395 S.W.3d 29, 40 (Mo. 2013). The Missouri Administrative Procedure Act allows an aggrieved person to challenge an agency’s decision on the grounds that the decision is contrary to law. Mo. Rev. Stat. § 536.150.1. The district court’s reasoning does not justify dismissal of the prisoners’ straightforward claim.

IV. The prisoners bring a viable *ex post facto* claim, because the state’s change from FDA-approved drugs to unregulated and illegally compounded drugs increases the risk of a painful execution and does so beyond Director Lombardi’s statutory discretion to determine the state’s execution method.

The prisoners plead that the defendants’ resort to compounded execution drugs and abandonment of FDA-regulated drugs, beginning in October 2013, places them at greater risk of suffering a painful execution. App. 121. Compounding pharmacies represent “an emerging, substandard drug industry responsible for making large quantities of unregulated, unpredictable and potentially unsafe drugs,” explains Dr. Sasich. App. 253. The defendants are relying on an unregulated “grey market” in which it is impossible to determine where the drug’s precursor ingredients come from, how those ingredients were manufactured, whether the ingredients have become contaminated, or how the final drug is compounded. App. 257-59. “The potential harm associated with the use of such contaminated or sub-potent drugs is extremely high.” App. 254. The prisoners do not need to show that Missouri’s method is cruel and unusual. It suffices if the prisoners have plausibly alleged a “significant risk of an increased punishment,” relative to the method of execution in effect at the time of their crimes. *Williams v. Hobbs*, 658 F.3d 842, 848 (8th Cir. 2011), quoting *Garner v. Jones*, 529 U.S. 244, 255 (2000).

The district court dismissed the claim. Add. 11. The court reasoned that the

Director of the Department of Corrections has statutory discretion to determine the state’s method of execution. *Id.* “The punishment—death—has not changed,” the court reasoned. “The prisoners had fair notice of that punishment, and of the Director’s discretion to determine the method of execution, when they committed their crimes.” *Id.*, quoting *In re Lombardi*, 741 F.3d 888, 896-97 (8th Cir. 2014) (en banc).

The district court reads *Lombardi* too sweepingly. *Lombardi* does not mean that the Director has limitless discretion to adopt whatever method of “lethal injection” or “lethal gas” he chooses under Mo. Rev. Stat. § 546.720.1. Nothing in the statute allows the Director to violate federal law, nor could it. *See* U.S. Const. Art. VI, Cl. 2 (“This Constitution, and the Laws of the United States which shall be made in pursuance thereof ... shall be the supreme law of the land”). In this instance, the defendants are violating federal law by making and administering a compounded drug that is “essentially a copy” of an FDA-approved drug, and by prescribing it without “a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 U.S.C. § 353a(a); 21 U.S.C. § 829(b); 21 U.S.C. § 353(b); 21 C.F.R. § 1306.04(a); *see also* Section III, above (describing federal violations). By violating federal law, Director Lombardi cannot be acting within the “discretion” that allows him to change Missouri’s execution method.

Neither does the mere existence of discretion defeat the prisoners' claim. The fact that a policy is discretionary does not mean that the ex post facto clause is indifferent when a change to the policy increases a prisoner's punishment after the crime. "The presence of discretion does not displace the protections of the Ex Post Facto Clause," the Supreme Court has held. *Garner*, 529 U.S. at 253. The rule of decision remains whether the changed policy creates "a significant risk of increasing [the prisoners'] punishment." *Id.* at 255. The prisoners have plausibly shown that it does, and dismissal was improper.

V. Due process entitles the prisoners to timely notice of material information about the drug that will be used to execute them.

The defendants' secretive conduct endangers the prisoners. Missouri uses illegal "copycat pharmaceuticals" provided by a "shadow pharmacy hidden behind the hangman's hood." *Nicklasson v. Lombardi*, No. 13-3664, Order denying rehearing, at 15 (8th Cir. Dec. 23, 2013) (Bye, J., dissenting). No evidence discloses where the drug's Active Pharmaceutical Ingredient comes from, the circumstances of its manufacture, its handling in the supply chain, or its manner of compounding. App. 260-61. Those questions implicate the prisoners' right to be free from cruel and unusual punishment. App. 261 ("Administering such an ingredient introduces an unacceptable risk of harm and is ill-advised."). That effect triggers the protections of due process: "Parties whose rights are to be affected are entitled to be heard; and in order that they may enjoy that right they must first be notified." *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972).

The state has managed to keep the needed evidence from the prisoners' hands, and then to defeat every stay motion by arguing that the prisoners lack the evidence they need. ECF Doc. 196 at 1-2 (noting "Catch-22" created by state's litigation conduct). Worse, the defendants insist **both** that the prisoners must specifically plead a "feasible, readily implemented alternative" **and** that the prisoners are entitled to no discovery on what methods or drugs are "reasonably available" to the Missouri Department of Corrections. App. 541, 543, 686-87;

Opposition to Winfield Motion for Stay of Execution (filed June 6, 2014), at 8.

The district court dismissed the claim in reliance on *Lewis v. Casey*, 518 U.S. 343 (1996), and *Williams v. Hobbs*, 658 F.3d 842 (8th Cir. 2011). Add. 17-18. The court reasoned that the right to access the courts affords only “the capability of bringing contemplated challenges to sentences or conditions of confinement.” Add. 17. Although the defendants’ conduct “may have hindered Plaintiffs’ ability to discover grievances and effectively litigate any challenge to the protocol,” the court observed, the defendants “have not obstructed Plaintiffs’ capability to file a suit.” *Id.* In fact, the district court claimed, “This lawsuit itself is evidence of Plaintiffs’ ability to challenge the protocol.” *Id.* The problem, of course, is that the state’s court-sanctioned obfuscation forecloses the prisoners from pleading a cognizable Eighth Amendment claim as the district court defines one. “Parties whose rights are to be affected … must first be notified.”” *Fuentes*, 407 U.S. at 80, and the notice must “permit adequate preparation for, an impending hearing,” *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 14 (1978).

The right to due process applies when the state’s action burdens the claimant’s life, liberty, or property. *Kentucky Dept. of Corr. v. Thompson*, 490 U.S. 454, 460 (1989). A reviewing court must then examine “whether the procedures attendant upon that deprivation were constitutionally sufficient,” using

the three-part framework of *Matthews v. Eldridge*, 424 U.S. 319 (1976). *Id.* Each part of the test weighs in favor of the prisoners.

A. The defendants' lethal injection protocol implicates the prisoners' life interest.

The means by which the defendants will execute the prisoners implicates their life interest in avoiding "unnecessary and wanton infliction of pain." *Gregg v. Georgia*, 428 U.S. 153, 173 (1976). Indeed, the Supreme Court in *Baze v. Rees*, 553 U.S. 35 (2008), squarely held that the Eighth Amendment forbids combinations of drugs that inflict unnecessary pain and suffering, concluding in that case that without a sedative, the injection of pancuronium bromide and potassium chloride would present "a substantial, constitutionally unacceptable risk of suffocation." *Id.* at 53. Procedural due process, in turn, protects the prisoners' right not to be executed in a manner that violates the Eighth Amendment. *Ohio Adult Parole Auth. v. Woodard*, 523 U.S. 272, 281 n.3 (1998) ("This substantive constitutional prohibition [against cruel and unusual punishment] implicate[s] due process protections.").

B. The prisoners' life interest entitles them to notice of material information about the lethal drug with which they will be executed.

Because the prisoners have a constitutional interest in avoiding an inhumane execution, the manner in which they are executed is subject to the requirements of due process. "For more than a century the central meaning of procedural due

process has been clear: ‘Parties whose rights are to be affected ... must first be notified.’” *Fuentes*, 407 U.S. at 80, quoting *Baldwin v. Hale*, 68 U.S. (1 Wall.) 223, 233 (1863). Notice is not an end in itself, but rather is intended “to apprise the affected individual of, and permit adequate preparation for, an impending ‘hearing,’” *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 14 (1978), during which he has “an opportunity to present [his] objections,” *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950). If the right to notice and a hearing is to have substance, “it must be granted at a time when the deprivation can still be prevented.” *Fuentes*, 407 U.S. at 81.

Due process in this case demands that the defendants disclose material information about the execution drug they intend to use. *Matthews v. Eldridge*, 424 U.S. 319, 335 (1976), sets out the three factors to be considered in making this determination:

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

All three factors favor the prisoners. First, their interest in vindicating their Eighth Amendment right is significant. “[D]eath is a different kind of punishment from any other which may be imposed in this country ... in both its severity and its

finality.” *Gardner v. Florida*, 430 U.S. 349, 357 (1977) (plurality opinion). Because the consequences of executing a prisoner in a cruel and unusual manner are “horrendous,” *Baze*, 553 U.S. at 117 (Ginsburg, J., dissenting), the prisoners’ private interest in avoiding unnecessary pain during death is “almost uniquely compelling,” *Ake v. Oklahoma*, 470 U.S. 68, 79 (1985). Far less weighty interests than that asserted here have enjoyed due process protection. *See, e.g., Goss v. Lopez*, 419 U.S. 565, 572-76 (1975) (protected interest against suspension from public school).

Second, the risk that the prisoners will be tortuously deprived of their life interest is substantial unless they receive a timely disclosure of information regarding the substances the defendants intend to inject into them. Four recent executions shed light on the substantial risk of serious harm that execution drug failure can cause. Twelve seconds into his execution in Oklahoma, which utilized a three-drug cocktail that included pentobarbital obtained from an unnamed compounding pharmacy within the state, Michael Lee Wilson uttered his chilling final words: “I feel my whole body burning.”⁵ A week later, Ohio executed Dennis McGuire with a combination of drugs never before used in lethal injection in the U.S., and he “struggled, made guttural noises, gasped for air and choked for about

⁵Rick Lyman, *Ohio Execution Using Untested Drug Cocktail Renews the Debate over Lethal Injections*, New York Times, Jan. 17, 2014, at A15.

10 minutes.”⁶ Clayton Lockett’s execution in Oklahoma in April was horribly botched: he regained consciousness, writhed, groaned, and took 43 minutes to die, reportedly from a heart attack.⁷ Similarly disturbing was the July 23 execution of Arizona prisoner Joseph Wood, who, having been denied a stay of execution on his First Amendment claim targeting the secrecy of the state’s execution drugs and personnel, suffered an execution that lasted 1 hour and 57 minutes, with Mr. Wood gasping for breath some 660 times.⁸

Considering these troubling events, there is a significant “value … [in] additional … procedural safeguards,” *Mathews*, 424 U.S. at 335—at a minimum, timely disclosure of the composition and origin of the drugs it intends to use. “The Department has not disclosed preliminary evidence and additional verification of production in a facility that is registered and inspected by FDA in any compounding process. Administering such an ingredient introduces an unacceptable risk of harm and is ill-advised.” App. 261 (per Dr. Sasich). As the

⁶Alan Johnson, *Inmate’s Death Called ‘Horrific’ Under New, 2-Drug Execution*, The Columbus Dispatch, Jan. 17, 2014, available at <http://www.dispatch.com/content/stories/local/2014/01/16/mcguire-execution.html>

⁷Katie Freckland, *Clayton Lockett writhed and groaned. After 43 minutes, he was declared dead*, The Guardian, April 30, 2014, available at <http://www.theguardian.com/world/2014/apr/30/clayton-lockett-oklahoma-execution-witness>.

⁸Michael Muskal, *How did Arizona execution go wrong*, Los Angeles Times, July 24, 2014.

Ninth Circuit explained in *Wood v. Ryan*, — F.3d —, No. 14-16310, 2014 WL 3563348, at *8 (9th Cir. Jul. 19, 2014), (stay vacated *Ryan v. Wood*, — S. Ct. —, No. 14A82, 2014 WL 3600362 (U.S. Jul. 22, 2014)):

Knowing the source and manufacturer of the drugs, along with the lot numbers and NDCs, allows the public to discern whether state corrections departments are using safe and reliable drug manufacturers.

By withholding material information about the drugs, the defendants “ensure[] [themselves] a way of using a protocol that a court can ‘never’ look at in any serious fashion, and [they] can ‘flout’ the requirement for a constitutionally sufficient protocol ‘without fear of repercussion.’” *Beaty v. Brewer*, 649 F.3d 1071, 1073 (9th Cir. 2011) (Reinhardt, J., dissenting from the denial of rehearing en banc). This is not merely “impairment of … litigating capacity,” *Lewis*, 518 U.S. at 355, but an effective foreclosure of any opportunity to litigate the merits of the prisoners’ claims. Meaningful judicial review is essential to preventing an erroneous deprivation of the prisoners’ life interest in a humane execution. *See, e.g., Baze*, 553 U.S. at 56 (concluding that, on the record evidence, petitioners had not demonstrated substantial risks of serious pain “[i]n light of these safeguards” that Kentucky follows).

With respect to the third *Mathews* factor, the defendants have no substantial countervailing interest in preventing courts from enforcing the Eighth Amendment by refusing to disclose the information about the lethal drug. Defendants cannot

seriously claim a significant interest in preventing adjudication of the protocol's lawfulness. Providing the prisoners with the material information they request imposes no "fiscal [or] administrative burdens" on the state of Missouri. *Mathews*, 424 U.S. at 335. The defendants' self-serving interest in protecting themselves from possible embarrassment, public scrutiny, or disclosure of actual unlawful behavior cannot be recognized by this Court as outweighing the prisoners' right to a humane execution. Nor does it serve the public, as the state's citizens have a formidable interest in seeing that the defendants impose death sentences lawfully, humanely, and in conformity with the Constitution. There is no undue burden imposed by requiring the defendants to disclose material information about the lethal drugs, in order to allow judicial review at a "meaningful time and in a meaningful manner." *Hamdi v. Rumsfeld*, 542 U.S. 507, 533 (2004). The district court's ruling must be reversed.

VI. The district court wrongly dismissed the prisoners' deliberate indifference claim on the grounds that lethal injection is not a medical procedure, because the defendants are nevertheless indifferent to the prisoners' medical needs.

The prisoners plead that they have a serious medical need to be free from gratuitous pain during their executions, and that the defendants act with deliberate indifference to that need by subjecting them to the risks described by Drs. Sasich and Dr. Heath. App. 108, 204-05. That indifference gives rise to a viable Eighth and Fourteenth Amendment claim, independently of whether the state's protocol creates a "substantial risk of serious harm" under *Baze v. Rees*, 553 U.S. 35, 50 (2008). *See Estelle v. Gamble*, 429 U.S. 97, 104 (1976) ("[D]eliberate indifference to serious medical needs of prisoners constitutes the unnecessary and wanton infliction of pain proscribed by the Eighth Amendment."); *West v. Atkins*, 487 U.S. 42, 58 (1988) (Scalia, J., concurring) ("[A] physician who acts on behalf of the State to provide needed medical attention to a person involuntarily in state custody (in prison or elsewhere) and prevented from otherwise obtaining it, and who causes physical harm to such a person by deliberate indifference, violates the Fourteenth Amendment's protection against the deprivation of liberty without due process."); Michael B. Mushlin, *Rights of Prisoners* §§ 3:63, 3:68 (4th ed. Oct. 2011 Update).

The district court dismissed the claim. It reasoned that "Defendants are not addressing Plaintiffs' medical needs when carrying out executions" and that an

execution does not constitute “medical treatment.” Add. 12. But a deliberate indifference claim requires no such thing, even assuming that Missouri executions are non-medical despite their clinical features—using an anesthesiologist and a nurse, prescribing a drug, administering it intravenously and even through a central line if the physician considers it necessary, and all for the express purpose of ensuring a “rapid and painless death,” and App. 232; ECF Doc. 156-1, Doc. 163 at 12. The question is not whether state parties are carrying out a medical procedure; it is whether they are indifferent to a prisoner’s medical needs.

The Supreme Court’s opinion in *Helling v. McKinney*, 509 U.S. 25 (1993), illustrates this distinction. There, the Court held that the prisoner stated a viable claim because the prison subjected him to his cellmate’s cigarette smoke: “McKinney states a cause of action under the Eighth Amendment by alleging that petitioners have, with deliberate indifference, exposed him to levels of ETS [environmental tobacco smoke] that pose an unreasonable risk of serious damage to his future health.” *Id.* at 35. The defendants in *Helling* were not carrying out a medical procedure; they were merely indifferent to the prisoner’s medical needs when they failed to protect him from second-hand cigarette smoke. The same is true of the defendants here: whether or not the adjective “medical” describes Missouri’s lethal injection procedure, the well-pleaded claim is that the procedure subjects the prisoners to specific medical risks, that the defendants know of those

risks, and that they are deliberately indifferent to them. The district court's judgment must be reversed.

VII. Because the allowance of pre-execution judicial review is a core component of Missouri's execution procedures, the district court erred by dismissing the prisoners' claim that the defendants violate equal protection by routinely executing prisoners while stay remedies are pending.

The prisoners allege that the defendants violate the guaranty of equal protection by carrying out executions when stay proceedings are pending, in violation of a core aspect of their own written policy. App. 147-65, 211-15. Such deviations violate the Equal Protection Clause, because the prisoners are left without any assurance that the state will execute them in accordance with established and consistent procedures. *Cooey v. Kasich*, 801 F. Supp. 2d 623, 652-59 (S.D. Ohio 2011) (deviation from "core" aspects of written protocol violated equal protection); *In re Ohio Execution Protocol Litig.*, 840 F. Supp. 2d 1044, 1054-59 (S.D. Ohio 2012) (same).

Missouri's protocol forbids the defendants from even escorting the prisoner from the holding cell to the execution chamber if there is pending legal activity to halt the execution:

11:15 PM Director of the Department of Corrections/designee advises (ERDCC Warden) that (Inmate Name) may be escorted to the execution room if no stay is in place and no legal activity is in process to prevent the execution.

If there is pending legal activity to halt the execution process, (Inmate Name) will remain in his holding cell and there will be no IV or line established until authority is granted to do so by the Director of the Department of Corrections/designee.

App. 335-36. The same procedures permit an execution to proceed only when the Attorney General certifies that there are no “legal impediments” or other reasons that the execution should not proceed:

Department Legal Counsel/designee asks the attorney general/representative, “Are there any legal impediments or reasons why the lawful execution of (Inmate Name) should not proceed?”

App. 337 (procedure of 12:00 a.m.).

The defendants argued below that the Director may authorize an execution to proceed by granting the “authority to do so.” App. 336 (11:15 p.m. procedure). But the directive expressly cabins the Director’s power to give that authorization: the Director has that authority when “no stay is in place and no legal activity is in process to prevent the execution.” If the Director had such authority *during* the pendency of stay proceedings, then there would be no purpose served by language allowing him to do so in the absence of such proceedings.

When denying a stay of execution to Allen Nicklasson, the district court agreed that the protocol forbids executions during stay remedies. *See* ECF Doc. 196 at 10 (“Because Defendants have violated a portion of their protocol on one occasion does not mean Defendants are likely to do it again.”). Of course, later circumstances validated Mr. Nicklasson’s claim. Just as the state executed Joseph Franklin when stay remedies were pending in the district court, it executed Mr. Nicklasson when a motion for rehearing was pending in this Court. *Nicklasson v.*

Lombardi, Case No. 13-3664, Amended Order dated Dec. 23, 2013, at 2 (Bye, J., dissenting). The next month, it executed Herbert Smulls despite his stay proceedings in the U.S. Supreme Court; the defendants began the execution at 10:11 p.m. on January 29, 2014, thirteen minutes before the Supreme Court denied the stay application. *See* ECF Doc. 363 at 5-8, and accompanying exhibits.

A. The allowance of pre-execution judicial review is a “core” provision of the state’s execution procedures.

The district court did not repudiate its earlier holding that the state’s procedures forbid executions during the pendency of stay remedies. Nevertheless, it reasoned that the protocol language at issue is not a “core provision” of the procedure. Add. 19. Citing the relevant Ohio cases, the district court concluded that “core provisions” are limited to those which “pertain[] to properly administering and carrying out the executions of inmates,” such as preparing the drugs, preparing the inmate, administering the drugs, and deciding who participates in the execution. Add. 18-19, citing *Cooey v. Kasich*, 801 F. Supp. 2d 623, 645-50 (S.D. Ohio 2011), and *In re Ohio Execution Protocol Litig.*, 840 F. Supp. 2d 1044 (S.D. Ohio 2012).

But the authorities cited do not limit the concept of “core provisions” as the district court did. Core deviations are any which “subvert[] the key constitutional principles that control the execution process.” *In re Ohio Execution Protocol Litig.*, 840 F. Supp. 2d at 1049. “Core provisions” extend beyond the four corners

of the execution process itself; indeed, one “core provision” of the Ohio protocol is a requirement that the Director of the Department of Corrections authorize any “non-core” deviations from the protocol. *Id.* at 1053. The court merely “assumed arguendo” that certain other documentation requirements were “non-core.” *Id.*

The allowance of pre-execution judicial review is an intuitively “core” provision. Judicial review is key to ensuring that executions are humane, because it enforces compliance with constitutionally-required safeguards in written protocols. *E.g., Baze v. Rees*, 553 U.S. 35, 56 (2008) (concluding that, on the record evidence, petitioners had not demonstrated substantial risks of serious pain “[i]n light of these safeguards” that Kentucky follows). The protocol provision at issue affects the prisoners’ rights to be free from cruel and unusual punishment; the very purpose of a written protocol is to protect that right, and, indeed, the district court in earlier litigation ordered Missouri officials to establish a written protocol to allow before-the-fact judicial review. *See Taylor v. Crawford*, No. 05-4173-CV-C-FJG, 2006 WL 1779035, at *7-*9 (W.D. Mo. Jun. 26, 2006). That is why, contrary to the district court’s reasoning, the demonstrated case-by-case deviations from Missouri’s protocol “affect the risk of pain to which [the prisoners] would be subjected, and therefore the risk of being subjected to cruel and unusual punishment.” Add. 19, quoting *Towery v. Brewer*, 672 F.3d 650, 660 (9th Cir. 2012).

B. The prisoners need not show that the state’s conduct independently violates the Eighth Amendment.

The district court next erred by requiring the prisoners to demonstrate a free-standing Eighth Amendment violation in order to plead an equal protection claim. Add. 19. But no precedent requires an equal protection claim to include an Eighth Amendment violation as an element. To the contrary, it suffices to show that a state’s deviation from its procedures “burdens” or affects the prisoners’ Eighth Amendment or other constitutional rights. *See In re Ohio Execution Protocol Litig.*, 840 F. Supp. 2d at 1054, *aff’d*, 671 F.3d 601 (6th Cir. 2012) (upholding stay of execution because state must follow its own procedures even if those procedures do not violate the Eighth Amendment); *Arthur v. Thomas*, 674 F.3d 1257, 1263 (11th Cir. 2012) (“significant deviation” from protocol stated valid equal protection claim); *Towery*, 672 F.3d at 659 (rejecting the “broad proposition” that an equal protection violation requires a showing of cruel and unusual punishment). The prisoners are entitled to further proceedings on their claim.

CONCLUSION

WHEREFORE, for all the foregoing reasons, appellants respectfully request that the Court reverse the ruling and judgment below, and remand the case for further proceedings.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 32(a)(7)(C), the undersigned certifies that this brief complies with the applicable type-volume limitations of Federal Rules of Appellate Procedure 32(a). This brief was prepared using a proportionally spaced type (Times New Roman, 14 points). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), this brief contains 13,972 words, according to the word count function of WordPerfect X4 word processing software.

/s/ Joseph W. Luby

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CERTIFICATE OF SERVICE

I certify that the above and foregoing brief was served on the Court and opposing counsel via the ECF system on July 28, 2014. Additionally, I hereby certify that within five days of the acceptance of this brief by the Eighth Circuit, I will deliver ten paper copies to the Court and one paper copy to opposing counsel, Michael Spillane, of the Missouri Attorney General's office.

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